REMARKS

Claims 1-31 were originally filed with the application. By amendment herewith, claims 1, 9, 10, 24 and 25 are being amended.

In the March 21, 2003 Office Action, the Examiner rejected claims 1-31 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the Applicant regards as the invention. Appropriate claim amendments have been made to each independent claim (i.e., claims 1, 24, and 25) to remove the antecedent basis concerns raised by the Examiner. Applicant submits that this rejection has been overcome.

The Examiner also rejected independent claims 1, 24, and 25 under 35 U.S.C. §103(a) as being patentable over U.S. Patent No. 6,104,938 to Huiku, et al. in view of U.S. Patent No. 5,725,480 to Oosta, et al. The rejection is respectfully traversed and reconsideration and allowance are requested. Each independent claim is addressed below.

As presented, independent claim 1 is directed to a method for compensating for subject-specific variability in an apparatus utilized for non-invasive determination of light absorbing substances of a subject's blood. In this regard, such an apparatus includes an emitting means for emitting radiation at least two different wavelengths and a detector means for receiving such radiation, which is utilized to measure the light absorbing substances. The method includes the steps of calibrating the apparatus utilizing a nominal calibration (e.g., a calibration curve based on average values from a control group). Initial characterization measurements are then made that include measuring radiation (i.e., emitted by the emitter means) that is received by the detector means

without transmission through the tissue of a subject. Based on these characterization measurements, nominal characteristics are established that describe the conditions under which the nominal calibration is utilized. For example, but not by way of limitation, these nominal characteristics may include an intensity measurement of the received radiation. Reference data is stored indicative of these nominal characteristics. In-vivo measurements are made on living tissue of a subject wherein radiation transmitted by the emitter means through the living tissue of a subject is received by the detector means and measured. Based on the in-vivo measurements and the reference data, tissue induced changes in the nominal characteristics are determined. These tissue-induced changes are utilized to compensate for subject-specific variation by correcting the nominal calibration on the basis of such tissue-induced changes. Stated differently, one or more nominal characteristics are established that describe the conditions under which the apparatus is nominally calibrated. This step is performed "off-line" such that radiation transmitted between the light emitting means and light detecting means during the characterization is measured without transmission through tissue. The same characteristics are again established in in-vivo or "on-line" measurements (i.e., measurements of light transmitted through the subject's tissue). On the basis of the changes between the off-line and on-line measurements, the nominal calibration is altered to create a subject-specific calibration. This subject-specific calibration takes into account the differences in a transmitted signal caused by an individual subject, rather than relying on a nominal calibration suitable for an average member of a large group of subjects. Of note, determining tissue-induced changes between the on-line and off-line measurements typically requires that the reference data indicating the nominal characteristics be stored (e.g., in a sensor or control unit associated with the apparatus) for comparison purposes. As will be appreciated, storage of this data allows for establishing such nominal characteristics in the manufacturing stage, or, in conjunction with performing in-vivo measurements of a given subject.

Independent Claim 24 provides an apparatus for determining an amount of two or more light absorbing substances in the blood of a subject, wherein subject-specific variations are taken into account during calculation of those substances. The apparatus includes emitter means and detector means for transmitting and receiving at least two wavelengths of radiation. A first processing means processes the outputs from the detector means to produce a modulated signal for each wavelength. These modulated signals correspond to pulsating absorption of the radiation by arterial blood of a subject. A second processing means applies a predetermined calibration to the modulated signals to produce transformed modulation signals applicable to the Lambert-Beer model. A memory means stores nominal characteristics indicative of the predetermined calibration as applied to output signals from detected radiation that was not transmitted through tissue. A first compensating means determines tissue-induced changes in the nominal characteristics. In this regard, changes between output signals that have not passed through tissue and output signals that have passed through tissue are determined. A second compensating means corrects the predetermined calibration according to the tissue-induced changes to produce a subject-specific calibration. A calculation means utilizes the subject-specific calibration to determine subject specific blood substance amounts.

Independent Claim 25 is directed to a sensor having an emitter for emitting radiation at two or more wavelengths and a detector for detecting such radiation and producing two or more output signals. The sensor further includes a storage means for storing reference data that is indicative of nominal characteristics under which the sensor was nominally calibrated. In particular, the nominal characteristics describe conditions wherein radiation is transmitted between the emitter and detector without passing through living tissue. In this regard, the sensor stores information that may be utilized to identify tissue-induced changes in the nominal characteristics when radiation is

transmitted between the emitter and detector through living tissue. Accordingly, these changes may be utilized to correct a nominal calibration.

Each independent Claim allows for determining light absorbing substances of blood wherein subject-specific data is utilized to correct a nominal calibration. In this regard, conditions under which a nominal calibration is used are established for comparison purposes. These conditions relate to measurements of radiation transmitted between an emitter and detector free of transmission through living tissue. Subsequent measurements of radiation transmitted through living tissue may be compared to the established conditions to identify tissue-induced changes. These changes may then be utilized to correct a nominal calibration into a subject specific calibration.

Huiku does not disclose, inter alia, an apparatus having a nominal calibration that may be subsequently altered according to subject-specific variation(s). Huiku also fails to disclose or suggest performing an initial characterization measurement wherein radiation received by a detector means (i.e., from an emitter) is received without transmission through a subject's tissue in order to establish nominal characteristics, which describe the conditions under which the nominal calibration is utilized. Likewise, Huiku fails to establish the same characteristics during in-vivo measurements for comparison with the nominal characteristics such that tissue-induced changes may be determined. As no tissue-induced changes are determined, a nominal calibration cannot be altered to be subject-specific. As presented, Huiku simply provides a sensor that is capable of storing a calibration value for subsequent utilization. However, Huiku fails to disclose an apparatus or system wherein differences between off-line measurements and on-line measurements are utilized to alter a nominal calibration according to subject-specific variation(s).

Oosta does not suggest or disclose a methodology, apparatus, or sensor having the arrangement of claims 1, 24, or 25. For example, Oosta fails to disclose carrying out initial characterization measurements wherein radiation that does not pass through the tissue of a subject is measured to establish nominal characteristics. That is, Oosta does not disclose performing off-line measurements to determine nominal characteristics that describe conditions under which a nominal calibration is utilized. Furthermore, Oosta fails to disclose or suggest comparisons of in-vivo measurements (e.g., measured radiation that has passed through the tissue of a subject) with reference data indicative of such nominal characteristics. Accordingly, Oosta cannot determine tissue-induced changes based on in-vivo measurements and stored reference data indicative of nominal characteristics, which describe the conditions under which a nominal calibration is utilized.

Applicant submits that, the combination of Huiku and Oosta as suggested by the Examiner fails to teach the subject matter as claimed in independent claims 1, 24, and 25. For instance, neither of the cited references discloses or suggests, inter alia, performing an off-line measurement of radiation that does not pass through the tissue of a subject for establishing nominal characteristics that describe the conditions under which a nominal calibration is utilized. Further, neither reference discloses or suggests storing reference data indicative of these nominal characteristics, or comparison of such data with values from in-vivo/on-line measurements to alter the nominal calibration for subject-specific changes. Therefore, Applicant respectfully submits that this rejection should be withdrawn.

Based upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation

would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

MARSH FISCHMANN & BREYFOGLE LLP

By: _____

Russell T. Manning
Registration No. 51,260
3151 South Vaughn Way, Suite 411
Aurora, Colorado 80014
Telephone: (720) 562-5502
Facsimile: (720) 406-0520

Date: July 21, 2003